



IPW

Atty. Dkt. No. 066683-0196

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert MARTUZA et al
Title: REPLICATION-COMPETENT HERPES SIMPLEX
VIRUS MEDIATES DESTRUCTION OF
NEOPLASTIC CELLS
Appl. No.: 10/748,233
Filing Date: 12/31/2003
Examiner: J. Woitach
Art Unit: 1632

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits.

RELEVANCE OF EACH DOCUMENT

Any document listed on the attached PTO/SB/08 was cited as being relevant during the prosecution of the corresponding Japanese application.

All of the documents are in English.

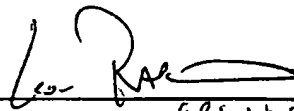
Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

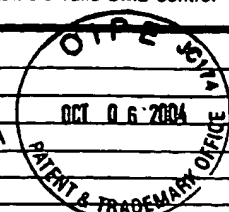
Date 10/4/04

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

By 
Reg No 93415
Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

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Substitute for form 1449B/PTO				Complete if Known		
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: October 6, 2004 (use as many sheets as necessary)				Application Number	10/748,233	
				Filing Date	12/31/2003	
				First Named Inventor	Robert MARTUZA	
				Group Art Unit	1632	
				Examiner Name	J. Weitach	
Attorney Docket Number	066683-0196					
Sheet	1	of	1			



U.S. PATENT DOCUMENTS						
Examine r Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS								
Examine r Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				

NON PATENT LITERATURE DOCUMENTS			
Examine r Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
		James M. MARKERT M.D. et al., "Reduction and Elimination of Encephalitis in an Experimental Glioma Therapy Model with Attenuated Herpes Simplex Mutants that Retain Susceptibility to Acyclovir", Neurosurgery, Vol. 32, No. 4, April 1993, pp. 597-603.	
		David J. GOLDSTEIN et al., "Herpes Simplex Virus Type 1-Induced Ribonucleotide Reductase Activity Is Dispensable for Virus Growth and DNA Synthesis: Isolation and Characterization of an ICP6 lacZ Insertion Mutant", Journal of Virology, Vol. 62, No. 1, Jan. 1988, pp. 196-205.	
		Richard J. WHITLEY et al., "Replication Establishment of Latency, and Induced Reactivation of Herpes Simplex Virus γ ₁ 34.5 Deletion Mutants in Rodent Models", J. Clin. Invest. Volume 91, June 1993, pp. 2837-2843	
		Cynthia A. BOLOVAN et al., "ICP34.5 Mutants of Herpes Simplex Virus Type 1 Strain 17syn+ Are Attenuated for Neurovirulence in Mice and for Replication in Confluent Primary Mouse Embryo Cell Cultures", Journal of Virology, Jan. 1994, Vol. 68, No. 1, pp. 48-55.	

Examiner Signature		Date Considered	7/27/06
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document.

⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 18 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.



SPW

Atty. Dkt. No. 066683-0196

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert MARTUZA et al

Title: REPLICATION-COMPETENT HERPES SIMPLEX
VIRUS MEDIATES DESTRUCTION OF NEOPLASTIC
CELLS

Appl. No.: 10/748,233

Filing Date: 12/31/2003

Examiner: Not yet assigned

Art Unit: 1632

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Submitted herewith on Form PTO/SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56. A copy of each listed document is being submitted to comply with the provisions of 37 CFR §1.97 and §1.98.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(b), before the mailing date of the first Office Action on the merits, and within three (3) months of the mailing date of the foreign search report.

RELEVANCE OF EACH DOCUMENT

All of the documents are in English.

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO/SB/08 be returned in accordance with MPEP §609.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 CFR §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

Respectfully submitted,

Date 23 July 2004

By S. A. Bent

FOLEY & LARDNER LLP
Customer Number: 22428
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

Under the Paperwork Reduction Act of 1995, no persons are required to respond to a collection of information unless it contains a valid OMB control number.

Substitute for form 1449B/PTO		Complete if Known	
INFORMATION DISCLOSURE STATEMENT BY APPLICANT Date Submitted: July 23, 2004 (use as many sheets as necessary)		Application Number	10/748,233
		Filing Date	12/31/2003
		First Named Inventor	Robert MARTUZA
		Group Art Unit	1632
		Examiner Name	Not yet assigned
Sheet 1 of 1	Attorney Docket Number	066683-196	

U.S. PATENT DOCUMENTS						
Examiner Initials*	Cite No. ¹	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear
		Number	Kind Code ² (if known)			

FOREIGN PATENT DOCUMENTS								
Examiner Initials*	Cite No. ¹	Foreign Patent Document			Name of Patentee or Applicant of Cited Documents	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T ⁶
		Office ³	Number ⁴	Kind Code ⁵ (if known)				
ju	A1		WO 92/03563		CENTRAAL DIERGENEESKUNDIG INSTITUUT	3/5/1992		
ju	A2		WO 96/39841		GEORGETOWN UNIVERSITY	12/19/1996		

NON PATENT LITERATURE DOCUMENTS			
Examiner Initials*	Cite No. ¹	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.) date, page(s), volume-issue number(s), publisher, city and/or country where published.	T ⁶
ju	A3	International Search Report not published article	
	A4	Klaus ROEMER et al., "Transduction of foreign regulatory sequences by a replication-defective herpes simplex virus type 1: The rat neuron-specific enolase promoter", Virus Research 35 (1995) pp. 81-89.	
	A5	Shin-ichi MIYATAKE et al., "Transcriptional Targeting of Herpes Simplex Virus for Cell-Specific Replication", Journal of Virology, Vol. 71, No. 7, July 1997, pp. 5124-5132.	
	A6	R.G. VILE et al., "Targeting of cytokine gene expression to malignant melanoma cells using tissue specific promoter sequences", Annals of Oncology 5 (Suppl. 4), S59-S65, 1994.	
	A7	C.A. KEECH et al., "Analysis of Rat Prolactin Promoter Sequences that Mediate Pituitary-Specific and 3', 5'-Cyclic Adenosine Monophosphate-Regulated Gene Expression in Vivo", Vol. 3, No. 5, Mol. Endo. 1989, pp. 832-839.	
	A8	Christophe LEFEVRE et al., "Tissue-specific expression of the human growth hormone gene is conferred in part by the binding of a specific trans-acting factor", The EMBO Journal, vol. 6, no. 4, pp. 971-981, 1987.	
	A9	Shigeki KURIYAMA et al., "A Potential Approach for Gene Therapy Targeting Hepatoma Using a Liver-Specific Promoter on a Retroviral Vector", Cell Structure and Function, 16: (1991) pp. 503-510.	
	A10	Richard G. VILE et al., "In Vitro and in Vivo Targeting of Gene Expression to Melanoma Cells", Cancer Research, 53, pp. 962-967, 1993.	
	A11	Y. MIYAO et al., "Selective expression of foreign genes in glioma cells: use of the mouse myelin basic protein gene promoter to direct toxic gene expression", Journal of Neuroscience Research, vol. 36, 1993, pp. 472-479.	

Examiner Signature	<i>Joe W. Winters</i>	Date Considered	9/27/06
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² See attached Kinds of U.S. Patent Documents. ³ Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). ⁴ For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. ⁵ Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. ⁶ Applicant is to place a check mark here if English language Translation is attached.

Burden Hour Statement: This form is estimated to take 2.0 hours to complete. Time will vary depending upon the needs of the individual case. Any comments on the amount of time you are required to complete this form should be sent to the Chief Information Officer, U.S. Patent and Trademark Office, P.O. Box 1450, Alexandria, VA 22313-1450. DO NOT SEND FEES OR COMPLETED FORMS TO THIS ADDRESS. SEND TO: Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450.

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant: Robert MARTUZA et al.
Title: REPLICATION-COMPETENT HERPES
SIMPLEX VIRUS MEDIATES DESTRUCTION
OF NEOPLASTIC CELLS
Div. Appln. Of: 09/625,509, filed 07/25/00
Appln . No.: Unassigned
Filed: 12/31/03
Examiner: Unassigned

INFORMATION DISCLOSURE STATEMENT
UNDER 37 CFR §1.56

Commissioner for Patents
Box PATENT APPLICATION
Washington, D.C. 20231

Sir:

Submitted herewith on Form PTO-SB/08 is a listing of documents known to Applicants in order to comply with Applicants' duty of disclosure pursuant to 37 CFR §1.56.

As provided in 37 CFR §1.98(d), copies of the documents are not being provided since they were previously submitted to the United States Patent & Trademark Office in the above-identified parent application.

The submission of any document herewith, which is not a statutory bar, is not intended as an admission that such document constitutes prior art against the claims of the present application or that such document is considered material to patentability as defined in 37 CFR §1.56(b). Applicants do not waive any rights to take any action which would be appropriate to antedate or otherwise remove as a competent reference any document which is determined to be a *prima facie* art reference against the claims of the present application.

TIMING OF THE DISCLOSURE

The listed documents are being submitted in compliance with 37 CFR §1.97(d), before payment of the issue fee.

RELEVANCE OF EACH DOCUMENT

Applicants respectfully request that any listed document be considered by the Examiner and be made of record in the present application and that an initialed copy of Form PTO-SB/08 be returned in accordance with MPEP §609.

STATEMENT

The undersigned hereby states in accordance with 37 C.F.R. §1.97(e)(1) that each item of information contained in this information disclosure statement was first cited in any communication from a foreign patent office in a counterpart foreign application not more than three (3) months prior to filing of this Statement.

The Commissioner is hereby authorized to charge any additional fees which may be required regarding this application under 37 C.F.R. §§ 1.16-1.17, or credit any overpayment, to Deposit Account No. 19-0741. Should no proper payment be enclosed herewith, as by a check being in the wrong amount, unsigned, post-dated, otherwise improper or informal or even entirely missing, the Commissioner is authorized to charge the unpaid amount to Deposit Account No. 19-0741.

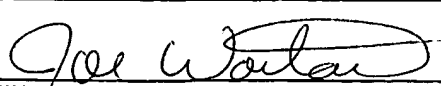
Respectfully submitted,

Date 31 December 2003

By S. A. Bent

FOLEY & LARDNER
Washington Harbour
3000 K Street, N.W., Suite 500
Washington, D.C. 20007-5143
Telephone: (202) 672-5404
Facsimile: (202) 672-5399

Stephen A. Bent
Attorney for Applicant
Registration No. 29,768

Form PTO-1449 (MODIFIED)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTY. DOCKET NO. 066683/0196		SERIAL NO. Unassigned		
INFORMATION DISCLOSURE CITATION (Use several sheets if necessary)				APPLICANT Robert MARTUZA et al				
				FILING DATE 12/31/2003		GROUP ART UNIT Unassigned		
U.S. PATENT DOCUMENTS								
EXAMINER INITIAL	REF	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB- CLASS	FILING DATE IF APPROPRIATE	
gw	A1	5,728,379	03/98	Martuza et al.	424	93.2		
FOREIGN PATENT DOCUMENTS								
	REF	DOCUMENT NUMBER	DATE	COUNTRY	CLASS	SUB- CLASS	TRANSLATION	
							YES	NO
OTHER DOCUMENTS (Including Author, Title, Date, Pertinent Pages, Etc.)								
gw	A2	Toda et al. "Treatment of Human Breast Cancer in a Brain Metastatic Model by G207, a Replication-Competent Multitumored Herpes Simplex Virus 1", <i>Human Gene Therapy</i> 9:2177-2185 (October 10, 1998).						
	A3	Chahlavi et al. "Replication-Competent Herpes Simplex Virus Vector G207 and Cisplatin Combination Therapy for Head and Neck Squamous Cell Carcinoma", <i>Neoplasia</i> 1(2):162-169 (June 2, 1999)						
	A4	Toda et al. "Herpes Simplex Virus as an <i>in Situ</i> Cancer Vaccine for the Induction of Specific Anti-Tumor Immunity", <i>Human Gene Therapy</i> 10:385-393 (February 10, 1999).						
	A5	Nilaver et al. "Delivery of herpesvirus and adenovirus to nude rat intracerebral tumors after osmotic blood-brain barrier disruption", <i>Proc. Natl. Acad. Sci. USA</i> 92:9829-9833 (October 1995).						
	A6	Neuwelt et al. "Delivery of ultraviolet-inactivated ³⁵ S-herpesvirus across an osmotically modified blood-brain barrier", <i>J. Neurosurg</i> 74:475-479 (March 1991).						
	A7	Walker et al. "Local and systemic therapy of human prostate adenocarcinoma with the conditionally replicating herpes simplex virus vector G207", <i>Human Gene Therapy</i> , pages 1-28 (In Press Sept. 1999)						
	A8	XO Breakefield et al. "New Biologist", 3:203-218 (1991)						
EXAMINER 				DATE CONSIDERED 9/27/06				
* EXAMINER: Initial if citation considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include any copy of this form with next communication to applicant.								

FORM PTO 1449 (modified)

U.S. DEPARTMENT OF COMMERCE
PATENT AND TRADEMARK OFFICELIST OF REFERENCES CITED BY APPLICANT(S)
(Use several sheets if necessary)ATTY DOCKET NO.
66683/134/GEUNSERIAL NO.
08/478,800APPLICANT
Robert MARTUZA et al.FILING DATE
June 7, 1995GROUP
Unassigned

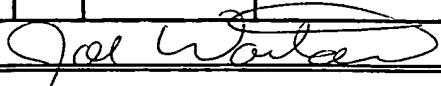
Date Submitted to PTO: September 13, 1995

OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)

720	A01	MCLAUCHLAN et al., "DNA Sequence Homology Between Two Co-Linear Loci On The HSV Genome Which Have Different Transforming Abilities", <i>The EMBO Journal</i> , Vol. 2:1953-1961, (1983)
	A02	SWAIN et al., "Herpes Simplex Virus Specifies Two Subunits Of Ribonucleotide Reductase Encoded By 3' Coterminal Transcripts", <i>Journal of Virology</i> , Vol. 57:802-808, (1986)
	A03	DUTIA, "Ribonucleotide Reductase Induced By Herpes Simplex virus Has A Virus-Specified Constituent", <i>J. Gen. Virol.</i> , Vol. 64:513-521, (1983)
	A04	MCLAUCHLAN et al., "Organization Of The Herpes Simplex Virus Type 1 Transcription Unit Encoding Two Early Proteins With Molecular Weights Of 140,000 And 40,000", <i>J. Gen. Virol.</i> , Vol. 64:997-1006, (1983)
	A05	MCGEOCH et al., "Comparative Sequence Analysis Of The Long Repeat Regions And Adjoining Parts Of The Long Unique Regions In The Genomes Of Herpes Simplex Viruses Types 1 And 2", <i>Journal of General Virology</i> , Vol. 72:3057-3075, (1991)
	A06	PERRY et al., "The DNA Sequences Of The Long Repeat Region And Adjoining Parts Of The Long Unique Region In The Genome Of Herpes Simplex Virus Type 1", <i>J. Gen. Virol.</i> , Vol. 69:2831-2846, (1988)
	A07	JACOBSON et al., "A Herpes Simplex Virus Ribonucleotide Reductase Deletion Mutant Is Defective For Productive Acute And Reactivable Latent Infections Of Mice And For Replication In Mouse Cells", <i>Virology</i> , Vol. 173:276-283, (1989)
	A08	SZE et al., "The Herpes Simplex virus Type 1 ICP6 Gene Is Regulated By A 'Leaky' Early Promoter", <i>Virus Research</i> , Vol. 26:141-152, (1992)
	A09	GOLDSTEIN et al., "Herpes Simplex Virus Type 1-Induced Ribonucleotide Reductase Activity Is Dispensable For Virus Growth And DNA Synthesis: Isolation And Characterization Of An ICP6 <i>lacZ</i> Insertion Mutant", <i>Journal of Virology</i> , Vol. 62:196-205, (1988)
	A10	NIKAS et al., "Structural Features Of Ribonucleotide Reductase", <i>Proteins: Structure, Function, and Genetics</i> , Vol. 1:376-384, (1986)
	A11	HUSZAR et al., "Partial Purification And Characterization Of The Ribonucleotide Reductase Induced By Herpes Simplex Virus Infection Of Mammalian Cells", <i>Journal of Virology</i> , Vol. 37:580-588, (1981)
	A12	CAMERON et al., "Ribonucleotide Reductase Encoded By Herpes Simplex Virus Is A Determinant Of The Pathogenicity Of The Virus In Mice And A Valid Antiviral Target", <i>J. gen. Virol.</i> , Vol. 69:2607-2612, (1988)
EXAMINER <i>John L. Feltner</i>		DATE CONSIDERED <i>9/27/06</i>

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609; Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

BEST AVAILABLE COPY

Sheet <u>2</u> of <u>2</u>																											
FORM PTO 1449 (modified) U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE LIST OF REFERENCES CITED BY APPLICANT(S) (Use several sheets if necessary) Date Submitted to PTO: September 13, 1995	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 50%; padding: 2px;">ATTY DOCKET NO. 66683/134/GEUN</td> <td style="width: 50%; padding: 2px;">SERIAL NO. 08/478,800</td> </tr> <tr> <td colspan="2" style="padding: 2px;">APPLICANT Robert MARTUZA <i>et al.</i></td> </tr> <tr> <td style="padding: 2px;">FILING DATE June 7, 1995</td> <td style="padding: 2px;">GROUP Unassigned</td> </tr> </table>	ATTY DOCKET NO. 66683/134/GEUN	SERIAL NO. 08/478,800	APPLICANT Robert MARTUZA <i>et al.</i>		FILING DATE June 7, 1995	GROUP Unassigned																				
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APPLICANT Robert MARTUZA <i>et al.</i>																											
FILING DATE June 7, 1995	GROUP Unassigned																										
OTHER DOCUMENT(S) (Including Author, Title, Date, Pertinent Pages, Etc.)																											
<div style="text-align: center;">240</div>	<table border="1" style="width: 100%; border-collapse: collapse;"> <tr> <td style="width: 10%; padding: 2px;">A13</td> <td style="padding: 2px;"> MCGEOCH <i>et al.</i>, "Sequence Determination And Genetic Content Of The Short Unique Region In The Genome Of Herpes Simplex Virus Type 1", <i>J. Mol. Biol.</i>, Vol. 181:1-13, (1985) </td> </tr> <tr> <td style="padding: 2px;">A14</td> <td style="padding: 2px;"> MCGEOCH <i>et al.</i>, "Complete DNA Sequence Of The Short Repeat Region In The Genome Of Herpes Simplex Virus Type 1", <i>Nucleic Acids Research</i>, Vol. 14:1727-1745, (1986) </td> </tr> <tr> <td style="padding: 2px;">A15</td> <td style="padding: 2px;"> MCGEOCH <i>et al.</i>, "The Complete DNA Sequence Of The Long Unique Region In The Genome Of Herpes Simplex Virus Type 1", <i>J. gen. 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